

# ***Future Research Needs***

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**Number XX**

## **Presentation of Future Research Needs**

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The information in this report is intended to help health care researchers and funders of research make well-informed decisions in designing and funding research and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of scientific judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical research and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances.

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## **Financial Disclosure Statement**

None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

## Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

An important part of evidence reports is to not only synthesize the evidence, but also to identify the gaps in evidence that limited the ability to answer the systematic review questions. AHRQ supports EPCs to work with various stakeholders to identify and prioritize the future research that are needed by decisionmakers. This information is provided for researchers and funders of research in these Future Research Needs papers. These papers are made available for public comment and use and may be revised.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The evidence reports undergo public comment prior to their release as a final report.

We welcome comments on this Future Research Needs document. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

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# Presentation of Future Research Needs

## Structured Abstract

**Objective:** To recommend a more standardized and systematic approach to presenting and organizing future research needs in Future Research Needs (FRN) documents.

**Methods:** A workgroup representing five of the eight ARRA-funded Evidence-based Practice Centers (EPCs) that are engaged in future research needs work reviewed prior effort on this topic and prepared a set of draft recommendations and frameworks, which were circulated to the remaining EPCs. Feedback on the working version was obtained from the EPC program at the May 2011 EPC meeting. All feedback was incorporated into the final report.

**Findings:** The workgroup developed separate frameworks for methods-related FRN recommendations and topic-specific FRN recommendations. Examples of methods-related issues include design issues, actions that facilitate the aggregation of results, inclusion of multiple disciplinary perspectives, and subgroup analysis. For topic-related FRNs, the PICOTS (Patient, Intervention, Comparator, Outcomes, Timing, and Setting) formulation should be used for each topic. The level of detail in presenting FRN recommendations will vary with the topic. Research in some areas may have sufficiently developed to the point where the gap can be precisely defined. EPCs should exercise judgment in determining the level of detail based on their understanding of the state of the science. The FRN should be presented in tiers rather than as a numerical ranking and should include a clear rationale for prioritization, based on considerations such as societal burden, feasibility, and likelihood of effect. An analytic framework should be used, if possible, and may be adapted. Specific recommendations for research design considerations should be made judiciously and framed as suggestions. Like the description of the future research need, the detail for these research design considerations may vary with the circumstance and topic. The executive summary should include the FRNs with the rationale for prioritization, without the PICOTS or research design considerations.

# Contents

<b>Background and Rationale</b> .....	1
Aims .....	2
<b>Methods</b> .....	3
<b>Results</b> .....	4
Review of Initial Eight FRN Reports.....	4
Tufts EPC Methods Report .....	4
RTI Methods Project .....	5
Panel Statements, NIH Consensus Development Conferences .....	6
<b>Recommendations</b> .....	7
General Recommendations .....	7
FRN Methods Framework .....	7
FRN Topics Framework .....	8
Considerations for Research Designs .....	9
<b>Conclusion</b> .....	10
<b>References</b> .....	11
<b>Abbreviations</b> .....	13
 <b>Tables</b>	
Table 1. Potential Issues For Methods Recommendations .....	7

## Background and Rationale

In 1997 the Agency for Healthcare Research and Quality (AHRQ) established a network of Evidence-based Practice Centers (EPCs) to produce systematic reviews intended to improve the quality of healthcare. Through the systematic review of available published literature, gaps in the evidence base are identified and included in the final evidence review. In 2010, eight EPCs with American Recovery and Reinvestment Act (ARRA) funding were charged with developing Future Research Needs (FRN) documents, which are stand-alone documents that build from the gaps identified by the evidence review to develop and prioritize future research needs based on stakeholder input. These documents are intended to inform researchers and those who fund research about the kinds of research that are most needed by decisionmakers. These initial FRN documents covered a range of topics, reflecting the areas of concentration of these eight EPCs. Some recommendations identified specific research topics, while others identified methodological issues common to many topics (e.g., measurement).

The goal of these FRN documents is to encourage further research based on the shortcomings identified in the Comparative Effectiveness Reports (CERs). We walk a fine line between stimulating action and appearing overly prescriptive. The question of the ‘desirable’ level of detail in laying out future research needs is related to larger questions of:

- Who is the primary audience for the reports (funding agencies, researchers)?
- Is the prioritization activity a technical exercises in which solutions (highly specified research studies to address research gaps) are found?

or

- Are stakeholders engaged in a prioritization activity that leads to insights and broad understanding of research gaps?

These questions may also be related to the strength of the evidence base in the underlying field of research. It is possible that fields with a large evidence-base are more amenable to focused prioritization efforts that yield highly specified research questions.

Stakeholder perspective offers some clues to resolving these questions. For example, the future research needs report on weight gain in pregnancy offered the following narrative: “Stakeholders were reluctant to dictate a specific form of study design because they felt that many of the research areas were at a nascent stage that might benefit from a multiplicity of approaches. In addition, while the group was inspired to map the identified research priorities to study approaches, they were reluctant to specify a single, correct next step. They expressed confidence in the collective energy and creativity of the scientific community, suggesting that agencies and organizations seeking to advance research in this area solicit and amply fund investigator-initiated research rather than pre-specifying study designs to answer high priority questions. Likewise there was confidence that robust expertise and appropriate study populations are available to realize answers to the prioritized questions quickly in order to bring practical tools and new knowledge to advancing the care of women and their children.”<sup>1</sup>

Stakeholder reactions varied for other topics. For example, members of the stakeholder panel on treatment for localized prostate cancer<sup>2</sup> took into account two large, lengthy randomized controlled trials that were then underway and sought to identify potential studies and research designs that could enrich the evidence base while awaiting the results of those trials. They also shifted the emphasis from specific treatments to determining which patients should be treated and when, because of their concern about substantial overtreatment in this patient population.

In addition to the pilot work in FRN documents, recognizing that this was a new area of work, these eight centers were also engaged in methodological development to provide an underpinning for eventual programmatic guidance. One of these projects was devoted to defining an optimal format for presenting research needs.<sup>3</sup>

As a result of these early experiences in piloting approaches to FRN development and prioritization, and exploration of methods, AHRQ has identified the need for program guidance on a structured and consistent method for presenting FRNs. Initial efforts have been made to create guidance, but initial experience has suggested that further refinements are indicated.

## **Aims**

This project will explore the way in which recommendations for FRNs can be best organized and presented across a variety of topics. It will delineate the elements and presentation that are most helpful in an evidence report versus future research needs document.

In the context of the FRN document, this relates specifically to the way the prioritized list of research needs (the “future research needs”) are presented. Early experience suggests two categories of research gaps, one related to the topic area and another related to methodological issues. This report will inform presentation elements and the level of detail that are optimal for each.



## Methods

A workgroup with representation across five EPCs currently engaged in future research needs work undertook the task to develop guidance in this area. The workgroup developed drafts and discussed them via conference calls.

To evaluate variation and to identify exemplars, they reviewed the initial set of FRN pilot reports<sup>1, 2, 4-9</sup> to assess how the research needs were presented. They also reviewed methods papers from the Tufts EPC<sup>3</sup> on defining an optimal framework for presenting research needs, based on systematic review and expert input, and the RTI EPC report<sup>10</sup> on the advantages and disadvantages of different study designs for FRN. The workgroup also scanned relevant sections of panel statements produced by NIH Consensus Development Conferences,<sup>11-15</sup> to assess their level of detail and scope. Lastly, the workgroup reviewed current content guidance for FRN documents, which were initially revised in response to methods work by EPCs in future research needs and consensus by EPCs at the November 2010 EPC meeting.

The group solicited EPC input from the other EPCS (both ARRA and non-ARRA) at the May 2011 EPC meeting. The draft report will subsequently undergo peer review by individuals from the EPC program, and a public posting period on the Effective Health Care website. Comments will be incorporated into the final report.

# Results

## Review of Initial Eight FRN Reports

Eight ARRA-funded EPCs developed pilot FRN documents based on a previously completed AHRQ systematic review. These eight reports were:

- Prioritizing Research Needs in Gestational Diabetes Mellitus (Johns Hopkins University EPC)<sup>4</sup>
- Integration of Mental Health/Substance Abuse and Primary Care (RTI International—University of North Carolina at Chapel Hill EPC)<sup>5</sup>
- Reducing the Risk of Primary Breast Cancer (Oregon EPC)<sup>6</sup>
- Outcomes of Maternal Weight Gain (Vanderbilt EPC)<sup>1</sup>
- Treatments of Common Hip Fractures (Minnesota EPC)<sup>7</sup>
- Clinically Localized Prostate Cancer (Blue Cross and Blue Shield Association Technology Evaluation Center EPC)<sup>2</sup>
- Comparative Effectiveness of Angiotensin Converting Enzyme Inhibitors or Angiotensin II Receptor Blockers Added to Standard Medical Therapy for Treating Stable Ischemic Heart Disease (Duke EPC)<sup>8</sup>
- Comparative Effectiveness of Percutaneous Coronary Interventions and Coronary Artery Bypass Grafting for Patients with Coronary Artery Disease (Tufts EPC)<sup>9</sup>

Of the initial eight Future Research Needs reports, half followed a broad, conceptual approach to identifying future needs and the other half used a more focused approach. The type of approach dictated the type and level of detail provided in laying out future needs. Reports that followed a broad, conceptual approach, specified future research needs at the level of research areas or questions and presented lists of research questions that were sometime organized as categories. These reports also tended to separate research questions from methodological considerations.

For example, the Vanderbilt EPC<sup>1</sup> supplemented the gaps identified in the original CER supplemented with additional gaps identified through a horizon scan of literature; they illustrated the content with an annotated causal framework. The Oregon EPC<sup>6</sup> categorized the research gaps identified in the original CER according to the most applicable element of the population(s), interventions, comparators, outcomes (PICO) framework. The Tufts EPC<sup>9</sup> expanded the initial list of gaps based on the original CER and feedback from a group of key informants with additions based on literature search and review of ongoing trials and refined in one-to-one interviews with key informants. They organized into the gaps four thematic areas: comparative effectiveness and safety of PCI (percutaneous coronary intervention) versus CABG (coronary artery by-pass graft), role of testing to inform choice of revascularization procedure, methods to enhance patient population, and methods for assessing performance.

## Tufts EPC Methods Report

The Tufts EPC methods report<sup>3</sup> on defining an optimal framework for presenting research needs offered a number of recommendations that serve as a jumping off point. (We have added some annotations.)

1. Provide succinct yet adequate description of methods and results following guidelines for reporting of healthcare research (for example, there are reporting guidelines for qualitative research and modeling). Aim for a level of detail similar to that found in papers addressed to a general medical audience.
2. Be cognizant of the importance of the face validity of the process. Justify the selection of the stakeholders who participated in identifying or prioritizing research needs, and be clear on their degree of engagement.
3. Consider reporting the results of the future research needs assessment at two levels of detail. A suggestion would be to first present general areas that merit future research without specifying research designs or specific details on e.g., PICOTS elements. A second set of results could further elaborate on potential research designs, details on PICOTS elements, or other details as applicable.
4. Frame the more specific set of results as “examples” rather than as strict recommendations. (For example, it may be better to avoid specific numerical rankings and cluster recommendations into high and medium categories,)
5. Avoid explicit prioritization of research needs when there are no clear differences in the perceived strength of alternative recommendations, but acknowledge strong beliefs when they exist. Consider a tiered presentation of future research needs by grouping them in thematic entities (after the priorities have been established).
6. Clearly define how “feasibility” of future research was assessed. It may be instructive to perform power analyses for specific research designs for a range of assumptions, and compare with the size of existing studies in the field.

## **RTI EPC Methods Project**

The RTI EPC methods project<sup>10</sup> on the advantages and disadvantages of different study designs for FRN discusses the terminology and presentation that could be used in FRN reports to describe study design considerations. The paper outlines common terminology for study designs and criteria for consideration of study designs. These criteria include resource use, size, and duration; availability of data and ability to recruit; ethical, legal and social issues; and advantages of study design for producing a valid result. Points taken from the paper for consideration by the workgroup include:

- Study design consideration comments may assist researchers and funders in determining whether to examine a given research question and guide the resources needed to address the research need. We anticipate that this information will provide a starting point for study planning and stimulate discussion. The FRN documents are intended to stimulate additional discussion among researchers and stakeholders, not truncate debate or planning. We do not intend that the future research considerations be prescriptive or exclude creative study designs or innovative use of existing data for CER.
- The criteria and terminology comments are generic, and will almost certainly need to be modified in a given FRN exercise, given the clinical and policy context of the condition under consideration.
- A degree of flexibility is necessary to apply these guidelines to considerations of study designs for future research needs. The advantages and disadvantages of a study design might change depending on the study question or the setting. The resources required for a study design depend on the intervention proposed. In addition, some study designs could be better suited for certain future research needs than other designs. Considerations

should include an understanding of the context of the research including the nature of the factor being investigated and potential utility and quality of the data.

## **Panel Statements, NIH Consensus Development Conferences**

The NIH Consensus Development Program organizes conferences generate evidence-based consensus statements addressing controversial issues important to healthcare providers, policymakers, patients, researchers, and the general public. The final key question of each NIH Consensus Development Conference relates to research needs, based on the evidence presented in these conferences. The workgroup scanned the relevant portions of these panel statements.

The scope of questions asked was variable and depended on the state of the science.

Examples include:

- Preventing Alzheimer's Disease and Cognitive Decline. If recommendations for interventions cannot be made currently, what studies need to be done to provide the quality and strength of evidence necessary to make such recommendations to individuals?<sup>12</sup>
- Vaginal Birth After Cesarean: New Insights. What are the critical gaps in the evidence for decisionmaking, and what are the priority investigations needed to address these gaps?<sup>13</sup>
- Inhaled Nitric Oxide Therapy for Premature Infants. What are the future research directions needed to better understand the risks, benefits, and alternatives to nitric oxide therapy for premature infants who receive respiratory support?<sup>11</sup>
- Lactose Intolerance and Health. What are the future research needs for understanding and managing lactose intolerance?<sup>14</sup>
- Enhancing Use and Quality of Colorectal Cancer Screening. What research is needed to make the most progress and have the greatest public health impact in promoting the appropriate use of colorectal cancer screening?<sup>15</sup>

The scope, detail, and organization of recommended research directions were variable across the panel statements. Methods of presentation included a numerical list, thematic approach, and narrative. Types of identified research needs were both methodological and topical and also included recommendations for infrastructure development as well as basic research in the field. Methods type research needs included use or development of consistent measures, reporting, and study design methodology. Often the description of the research need included a rationale that highlighted the importance of filling the need in terms of a patient outcome. Research design considerations were also frequently included, though the level of detail was also variable. While almost no one advocated a particular research design, many made mention of considerations related to power, subgroups, appropriate comparators, intervention details (timing, dosing, etc.), relevant outcomes, and contextual factors. When research designs were mentioned, they were frequently presented as an example among other potential approaches. For research designs presented as a recommendation, the panel included a rationale, and did not include specifics in terms of sample size or other details.

# Recommendations

## General Recommendations

The FRN, whether methodological or topic-specific in nature, should be presented as a top tier rather than a numerical list. The level of detail of the FRN description will depend on the state of the science, and EPCs should use their judgment based on their understanding of the topic and field.

Basic principles include:

- Rationale for prioritization if possible.
- Research design considerations for the FRN should be offered as suggestions only to avoid appearing overly prescriptive.

The workgroup recommended separating the presentation of two elements of potential future research: methods issues and specific topics. Methods issues tend to transcend specific topics. They should be ranked separately. Table 1 identifies elements that should be considered when addressing methods issues.

## FRN Methods Framework

The workgroup identified a number of potential methodological issues that an FRN might address. For each relevant issue, the FRN should address elements and level of detail and explain how this fills the evidence gap.

**Table 1. Potential Issues For Methods Recommendations**

Issues	Potential Details to be Addressed for Each Issue
Designs	<ul style="list-style-type: none"><li>• What research designs are most appropriate for specific questions? What are the barriers to conducting the optimal kind?</li><li>• How much information is needed regarding the study design and study elements such as intervention and patient characteristics?</li><li>• Where possible, FRN reports should allude to elements needed to improve the SOE from the initial CER.</li></ul>
Actions that facilitate aggregations of results	<ul style="list-style-type: none"><li>• For each clinical area, to facilitate comparisons and aggregation across studies, we need common measures and definitions for condition(s) under investigation, elements of interventions, major outcomes, and harms.</li><li>• Focus on harms as well as benefits when appropriate.</li></ul>
Inclusion of multiple perspectives	<ul style="list-style-type: none"><li>• Incorporate various disciplinary perspectives. The focus of different disciplines in terms of the emphasis on patients or treatments may vary.</li></ul>
Statistical analysis	<ul style="list-style-type: none"><li>• Specify interactions to identify differences in effects across subgroups.</li><li>• Specify when certain diagnostic categories should be in or out of a study. For example, the use of antipsychotics for persons with Tourette's syndrome.</li></ul>

An example of a methodological gap identified in an FRN relates to treatments for localized prostate cancer. Because of the lengthy course of this disease, some randomized controlled trials have been published with high crossover rates in which patients have taken the initiative to receive the treatment to which they were not randomized. This is understandable from the patient's perspective but may greatly reduce the ability to draw conclusions from the trial. Research was therefore recommended on "Exploring methods to increase patient adherence with randomization scheme." This might include surveys to help understand participants' decision-making; and measuring the effectiveness of approaches intended to reduce unplanned crossing

over to another arm. Research was also recommended to increase the use of statistical modeling and other advanced methods in studies on localized prostate cancer.

## FRN Topics Framework

The steps in this process may be summarized as follows:

- Include reason why the FRN is prioritized as high. May include criteria used (burden, feasibility, impact).
- Organize by PICOTS.
- Use analytic framework if possible, and adapt if needed. Consider including relevant issues such as subgroups, settings, and other contextual issues.
- Level of detail of FRN description depends on the state of the science.
- Research design considerations for the FRN should be offered as suggestions only to avoid appearing overly prescriptive.

The presentation of specific research topics should include a rationale as well as an organized presentation of each topic. Provide text description of why the prioritized questions are particularly urgent to be answered. Criteria for choosing topics should reflect why answers to the prioritized questions are particularly urgent. Proposed criteria include:

- Societal burden
  - Costs
  - Harms
- Feasibility of research
- Likelihood results will affect practice/policy (for patients as well as others)

The PICOTS formulation should be used to present each recommended topical research question in a separate table for each question. Graphical frameworks are often used in grants to clearly communicate ideas, linkages, and assumptions to demonstrate that the research proposed is well-integrated, well-reasoned, and appropriately designed to advance a field of research. Analytic frameworks have been used to structure comparative and systematic reviews but were not intended to guide discussions of future research, although work is underway to adapt them to FRNs when feasible. However, analytic frameworks depict the population, interventions, comparators, outcomes, timing, and settings (PICOTS) which are often key elements in research study designs. Future research chapters of CERs often mention the need for more research on special populations (including racial, ethnic, and genetic variations), settings (e.g., community or geographic), contextual features such as patient-provider communication and decisionmaking, and influencing factors as important topics for future research. Thus an analytic framework may be an effective method to display these considerations and their linkages to interventions and their outcomes. The report should employ a conceptual model or logic diagram when appropriate; not all FRN topics may be suitable for this. For example, research questions may address prevalence in subgroups. The model should be based on current thinking and not limited to what was in the parent report.

As part of the process of developing the top tier of FRNs, EPCs engage a wide variety of stakeholders who may identify a broad list of new potential research areas. It should be noted that these new areas of research will likely not be based on an assessment of the evidence (or lack of evidence) because they fall outside of the scope of the parent evidence report.

The level of detail in presenting recommendations will vary with the topic. Research in some areas may have sufficiently developed to the point where the gap can be precisely defined (e.g.,

testing a specific intervention or comparing two specific interventions). In other areas, the suggestions may be couched more broadly about types of questions or interventions. Likewise, the specificity of research design considerations may vary with the circumstance. In some cases, but not all, the appropriate design will be evident. There may be design trade-offs or specific issues to consider. Include any research design considerations or comments if relevant. For example, it would be inappropriate to recommend that you must do an RCT with X number of people, but it would be fitting to suggest (as opposed to recommend) that future research should be appropriately powered to study X subpopulation. EPCs will need to decide when the research design issues are sufficiently clear that they can be urged.

## **Considerations for Research Designs**

In looking at the entirety of literature, evidence reviews may uncover important insights regarding study designs that would help advance the science. Authors may want to consider including appropriate research considerations. Future research documents aim to delineate where there is an absence of studies and also to describe limitations of existing studies to the extent that researchers could improve upon those limitations. It can be a delicate balance to provide sufficient detail to be helpful to researchers while not being so prescriptive that research creativity and discovery are stifled. As opposed to identifying gaps in research, there may be important design issues to consider. When there are fatal flaws in prior study designs, future research needs documents should describe the flaws and potential design remedies in sufficient detail that interested researchers could improve their study designs accordingly. The amount of detail that should be shared in future research needs documents will depend on the topic and specifics of the report. In fields with relatively little evidence, a broad translational table presenting the spectrum of study designs that would be acceptable to inform certain research gaps may be most useful. In other areas, where there is a substantial body of literature, a deeper description of important flaws in existing studies that are hampering the strength of certainty in results is appropriate.

A common issue that future research documents can inform across topics addresses the role for observational studies and comments about the context in which observational studies may be suitable or even preferable for certain needs. For example, while there may be randomized controlled trials of screening, the question about the adverse consequences of screening (or the long-term effects) may be best answered through an observational study. While each report will differ on the extent to which details about study designs can be discussed, it is the general intent to describe important flaws and provide insights into possible solutions while promoting the creativity that advances discovery.

For specific details related to considerations of research designs in FRN documents, please refer to the RTI EPC methods paper on Advantages and Disadvantages of Different Study Designs for Future Research Needs.<sup>10</sup>

## **Conclusion**

The workgroup reviewed relevant documents from sources within the EPC program and external sources. The recommendations are based on the information gleaned from previous experience of the workgroup members, recommendations from methods work, and from exemplars of this work from multiple sources. We expect that further development in this area will continue as EPCs gain more experience in FRN work and the program receives feedback from stakeholders.

The methodology committee of the newly formed Patient Centered Outcomes Research Institute has been tasked with creating a translation table, which is intended to “provide guidance and act as a reference...to determine research methods that are most likely to address each specific research question (US Public Law 111-148, section 301). This additional guidance will also contribute to the development of FRN work within the EPC program.



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## **Abbreviations**

AHRQ	Agency for Healthcare Research and Quality
ARRA	American Recovery and Reinvestment Act
CER	Comparative Effectiveness Report
EPC	Evidence-based Practice Center
FRN	Future research needs
PICO	Population(s), Interventions, Comparators, Outcomes
PICOTS	Population(s), Interventions, Comparators, Outcomes, Timing, Settings